IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of Ken Tatebe et al. Application No.: 10/551,279 Filed: September 27, 2005 For: TEST PAPER AND POROUS MEMBRANE	))))))))))	**MAIL STOP** **APPEAL BRIEF - PATENTS** Group Art Unit: 1797 Examiner: Dean P. Kwak Appeal No.: Unassigned

APPEAL BRIEF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This appeal is from the decision of the Primary Examiner dated June 10, 2010 finally rejecting claims 1 and 4-7, which are reproduced as the Claims Appendix of this brief.

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The Commissioner is hereby authorized to charge any appropriate fees under 37 C.F.R. §§1.16, 1.17, 1.21 and 41.20 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800.

Table of Contents

I. Real Party in Interest

The present application is assigned to Terumo Kabushiki Kaisha. Terumo Kabushiki Kaisha is the real party in interest, and is the assignee of Application No. 10/551,279.

II. Related Appeals and Interferences

The Appellant's legal representative, or assignee, does not know of any other appeal or interferences which will affect or be directly affected by or have bearing on the Board's decision in the pending appeal.

III. Status of Claims

The application contains Claims 1-11. Claims 2, 3 and 8-11 have been canceled. Claims 1 and 4-7 are pending and stand finally rejected. This appeal is directed to all pending claims.

IV. Status of Amendments

There were no amendments submitted subsequent to the June 10, 2010 Final Office Action.

V. Summary of Claimed Subject Matter

Independent Claim 1 is directed to a test paper comprising a porous membrane for separating an object (such as a blood cell) from a sample (such as blood) by filtration and carrying thereon a reagent capable of giving a color by reaction with a specified component (such as glucose) in the sample, as discussed, for example, from line 16 of page 10 to line 7 of page 11 of this application. Claim 1 recites that the porous membrane has a first layer having a surface to which the sample is supplied and a second layer having a surface at which the sample is percolated and measured, as discussed, for example, from line 23 of page 11 to line 3 of page 12 of this application.

Independent Claim 6 is directed to a porous membrane comprising a first layer having a first surface and a second layer having a second surface, as also described, for example, from line 23 of page 11 to line 3 of page 12 of this application.

Claims 1 and 6 both recite that the first layer is made of large-sized pore portions, with a surface of the first layer being a smooth surface having apertures thereat, and the second layer is made of small-sized pore portions, with a surface of the second layer having apertures thereat, as described, for example, in lines 3-7 of page 12 of this application.

Claims 1 and 6 both also recite that the large-size pore portions have a section density of 40% or less, and that the small sized portions have a section density that exceeds 40%. The paragraph starting on line 8 of page 12 of this application describes this feature, while also defining how the section density is measured. Appellants note that this paragraph was amended in the response filed on March 2, 2009 to correct a typographical error.

Claims 1 and 6 both further recite that the first layer and the second layer together constitute a single membrane portion formed by a single casting operation. An exemplary method is disclosed on pages 21 through 27 of this application. In particular, a substrate, which has been formed by a single casting operation, is treated in a wet process including a membrane-forming stock solution feed step described from line 19 of page 21 to line 6 of page 25, an immersion-in-coagulation bath step described from line 7 of page 25 to line 16 of page 26, a rinsing step described from line 17 of page 26 to line 4 of page 27, and a drying step described from lines 5-11 of page 27. As discussed in the paragraph starting on line 4 of page 24 of this application, in the immersion-in-coagulation bath step, the membrane-forming stock solution has a charge ratio between a first component polymer and a water-soluble second component in the range of 1:1 to 1:3 so that the resultant small-sized pore portion occupies a portion corresponding to not less than half the membrane thickness. As further discussed in the paragraph starting on line 13 of page 4 of this application, the cast thickness is adjusted upon coating of the membrane-forming stock solution onto the substrate.

Claims 1 to 6 both also recite that the thickness of the porous membrane ranges from 50 to 200 μm. As discussed in the paragraph starting on line 4 of page

16 of the application, a thickness of the porous membrane within this range helps obtain satisfactory membrane strength, helps lessen an influence by an object that should be filtered, helps shorten a percolating time (developing time) of the sample, and helps allow the amount of the sample required to be small.

Claims 1 to 6 both also recite that a porosity of the porous membrane ranges from 60 to 95%. As discussed in the paragraph starting on line 13 of page 16 of the application, a porosity of the porous membrane within this range helps a sample and a reagent to be satisfactorily carried and helps obtain a satisfactory membrane strength.

Claims 1 to 6 both also recite that the first layer has an average pore size of 0.5 to 10 μm in the surface thereof, the first layer being located from the surface of the first layer within a range of 1/5 to 1/2 of a thickness of the porous membrane, and the second layer has an average pore size of 0.1 to 3.0 μm in the surface thereof, as described, for example, in lines 11-18 of page 15 and lines 4-12 of page 17 of the application. As discussed in the paragraph starting on line 19 of page 15 of the application, when the boundary between the first layer and the second layer is within this range and the average pore size of the first layer is larger than the average size of the second layer, the object that should be filtered out in the sample can be separated by filtration at a position distant from the surface (measuring surface) of the second layer. Thus, a reagent can be carried in a satisfactory manner. Additionally, as discussed in the paragraph starting on line 13 of page 17 of the application, the average pore size in the surface of the first layer within this range is favorable because a sample is able to rapidly infiltrate (percolate) and thus, no clogging with an object that should be filtered out occurs, while the average pore size in the surface of the second layer within this range is favorable because a sample is allowed to rapidly develop and thus the reagent can be carried satisfactorily.

Claims 1 and 6 also recite that the second layer has a surface glossiness according to JIS Z8741 not higher than 11. As discussed, for example, in the paragraphs bridging pages 12 and 13 and pages 20 and 21 of the specification, the inventors here have recognized that direct light reflected at the measurement surface of the test paper represents a noise when undergoing such a reflection absorbance measurement. In this regard, the application discloses modifying the surface glossiness of the measurement surface by, for example, the surface treatments

disclosed in the paragraph bridging pages 37 and 38 of the specification, prior to the wet forming steps. As further discussed in the first full paragraph on page 39 of the specification, the experimental results discussed in the application indicate that when the surface glossiness of the measuring surface according to JIS Z8741 is not higher than 11, the measuring accuracy in a high range of blood glucose level can be improved.

Claim 7 depends from Claim 6 and recites that a ratio between the average pore size in the surface of the first layer and the average pore size in the surface of the second layer is in the range of 1 to 6. As discussed in the paragraph starting on line 13 of page 16 of the application, a ratio between the average pore size in the surface of the first layer and the average pore size in the surface of the second layer within this range help with the rapid development of the sample.

VI. Grounds of Rejection to be Reviewed on Appeal

The June 10, 2010 Final Office Action (hereinafter the "Office Action") sets forth one ground of rejection. For purposes of appeal, the Board is being asked to review the following ground of rejection:

Claims 1 and 4-7 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Japanese Application Publication No. 2001-165930 (hereinafter "the Japanese publication"). Appellants cited the Japanese Publication and provided copies of the Japanese Publication along with an English translation thereof in a First Information Disclosure Statement filed with this application on September 27, 2005.

VII. Argument

As discussed in lines 9-11 of page 10 of the translation thereof, the Japanese publication discloses a test strip composed of a porous first layer and a second layer stacked one over the other. The first layer carries a reagent system that can react with a particular component in a specimen, the second layer has a function to filter off suspended matter in the specimen, and the test strip is adapted to measure at the second layer the particular component in the specimen by supplying the specimen from the first layer, as discussed in lines 11-17 of page 11 of the translation.

As further discussed in lines 2-9 of page 11 of the translation, the first layer is a porous membrane having an average pore size of from 3 to 10 μm, a membrane thickness of from 50 to 200 μm, a porosity of from 50 to 95%, and a ratio of an average pore size of the surface on the specimen-supplying side to an average pore size of the surface which is in contact with the second layer of 2.0 or greater. Additionally, as discussed in lines 10-18 of page 11 of the translation, the second layer is a porous membrane having an average pore size of from 0.1 to 2 μm, a membrane thickness of from 50 to 200 μm, a porosity of from 50 to 95%, and a ratio of an average pore size of the surface on the side where the particular component of the specimen is measured to an average pore size of the surface which is in contact with the first layer of 1.5 or greater.

A. Anticipation

The Examiner takes the position that the Japanese publication's disclosure that the average pore size in the first layer is from 3 to 10 μm is also a disclosure that the first layer has an average pore size of 0.5 to 10 μm in the surface thereof as recited in Claims 1 and 6 (Office Action, page 4, lines 5-6). However, the range disclosed in the Japanese publication refers to the average pore size in <u>the entire</u> first layer and not the average pore size in <u>the surface of</u> the first layer as recited. The Japanese publication does not disclose any specific values for the average pore size in the surface of the first layer, and thus fails to disclose an average pore size in the surface of the first layer which falls in the recited range.

The Examiner also takes the position that the Japanese publication's disclosure that the average pore size in the second layer is from 0.1 to 2 μm is also a disclosure that the second layer having an average pore size of 0.1 to 3.0 μm in the surface thereof as recited in Claims 1 and 6 (Office Action, page 4, lines 9-10). However, the range disclosed in the Japanese publication refers to the average pore size in <u>the entire</u> second layer and not the average pore size in <u>the surface of</u> the second layer as recited. The Japanese publication does not disclose any specific values for the average pore size in the surface of the second layer and thus fails to disclose an average pore size in the surface of the second layer which falls in the recited range.

For the above reasons, Appellants respectfully submit that the Examiner has clearly failed to establish that the test strip disclosed in the Japanese publication includes a first layer having an average pore size of 0.5 to 10 μm in the surface thereof or a second layer having an average pore size of 0.1 to 3.0 μm in the surface thereof.

B. Obviousness

The Examiner implicitly observes that the first and second layers do not together constitute a single membrane portion formed by a single casting operation as recited in Claims 1 and 6 (Office Action, page 6, lines 1-2). The Examiner goes on to assert that the use of one piece construction instead of the construction involving stacking two layers disclosed in the prior art would be merely a matter of obvious engineering design choice (Office Action, pages 6, lines 2-5). Appellants respectfully disagree. The recited test paper, like the test strip disclosed in the Japanese publication, includes two layers having differing properties. In the prior art, the layers with differing properties were obtained by forming the layers separately and stacking them together. By contrast, the present application discloses a wet process by which an integral substrate can be formed to have the layers with differing properties. Appellant's respectfully submit that, absent knowledge of the wet process disclosed in this application, an ordinarily skilled artisan would not have been able to integrally construct a test paper having two layers with differing properties. Appellants therefore respectfully submit that the Examiner has clearly failed to establish that the use of one piece construction to form the test strip disclosed in the Japanese publication would be a matter of obvious engineering design choice.

The Examiner also states that for a product-by-process claim defined by process steps by which a product is made, determination of patentability is based on the product itself and does not depend on its method of production (Office Action, page 6, lines 9-11), and therefore implies that there is no structural distinction between a membrane formed by stacking two layers together and a membrane formed by a single casting operation. This is clearly incorrect. When two layers are stacked together, the resultant product, unlike a product formed by a single casting operation, has a discontinuity and two additional surfaces, i.e., where the two layers

are in contact. Appellants therefore respectfully submit that the Examiner has clearly failed to establish that a membrane formed by stacking two layers together is structurally the same as a membrane formed by a single casting operation.

With respect to the section density of the pore portions in the first layer being 40% or less and the section density of the pore portions in the second layer being 40% or more, as recited in Claims 1 and 6, the Examiner implicitly observes that the Japanese publication does not directly address section density (Office Action, page 5, lines 7-9). The Examiner goes on to characterize section density as a result effective variable that an ordinarily skilled artisan would have optimized to be in the recited ranges as a matter of routine experimentation. Appellants respectfully disagree. As discussed in the Manual of Patent Examining Procedure § 2144.05, "(a) particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation." Appellants respectfully submit that the Japanese Publication makes no mention of section density at all, much less recognizes that section density is a result-effective variable. Appellants therefore respectfully submit that an ordinarily skilled artisan would not have looked determine an optimum or workable range for the section densities of the layers of the test strip disclosed in the Japanese Publication.

The Examiner also recognizes that the Japanese publication does not discuss the glossiness of any of the surfaces of the test strip (Office Action, page 4, lines 13-15). However, the Examiner asserts that it would have been obvious to modify the second layer of the test strip to have a surface glossiness according to JIS Z8741 not higher than 11. More specifically, the Examiner asserts that an ordinarily skilled artisan would select a material for the prior art test paper that would work best for its intended purpose, and also states that the surface glossiness of the test paper depends on the selected material for the test paper. Based on these assertions, the Examiner concludes that the surface glossiness of the prior art test paper was recognized in the prior art as a result effective variable, and that modifying the prior art test paper to have a surface glossiness as recited in this application would therefore have been obvious to an ordinarily skilled artisan.

As discussed above, it is well-established that a particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. Here, the Examiner has only alleged that the chosen material itself is recognized as a result effective variable. Additionally, while the Examiner has generally alleged that surface glossiness is material-dependent, the Examiner has provided no evidence that the glossiness is dependent solely on the type of material chosen for the test paper.

Moreover, even assuming the material chosen for the prior art test paper is a result effective variable, and the test paper's glossiness is influenced by the chosen material, it does not follow that the surface glossiness of the test paper is also a result effective variable. For example, an ordinarily skilled artisan would recognize that the surface glossiness of the test paper is influenced by not only the chosen material, but also any surface treatments, if any, performed on the prior art test paper.

The Examiner has not established that the test paper material selection only influences glossiness. Indeed, the test paper material likely influences a variety of characteristics of the test paper, and so it is not reasonable to assume that the selection of test paper would be done solely with an eye to optimizing glossiness. Indeed, the discussion of the prior art test paper makes no mention of its surface glossiness, much less treating the material to modify its surface glossiness, and the Examiner has provided no evidence or rationale for concluding that the prior art test paper, even if optimized by an ordinarily skilled artisan by selecting an optimum material, would have had a surface glossiness in the recited range.

For the above reasons, Appellants respectfully submit that the Examiner has clearly failed to establish that the surface glossiness of the prior art test paper was recognized as a result effect variable, or that modifying the surface glossiness with an eye toward optimization of the surface glossiness would have been a matter of routine experimentation.

In light of the foregoing, Appellants respectfully submit that the rejections of independent Claims 1 and 6 are improper and should be withdrawn. Appellants further submit that the rejections of the dependent claims are improper and should

be withdrawn in light of their dependency from improperly rejected independent claims.

C. Dependent Claims

With respect to dependent Claim 7, the Examiner takes the position that the disclosure in lines 5-17 of page 11 of the Japanese publication's translation is a disclosure that a ratio between the average pore size in the surface of the first layer and the average pore size in the surface of the second layer is in the range of 1 to 6 as recited in Claim 7 (Office Action, page 7, lines 5-7). However, that portion of the Japanese publication's translation does not address the ratio between the average pore size in the surface of the first layer and the average pore size in the surface of the second layer. The Examiner has therefore clearly failed to establish that the test strip disclosed in the Japanese publication includes a ratio between the average pore size in the surface of a first layer and the average pore size in the surface of a second layer in the range of 1 to 6. Appellants therefore respectfully submit that dependent Claim 7, in addition to being allowable in light of its dependence from allowable Claim 6, is independently allowable for this additional reason.

VIII. Claims Appendix

See attached Claims Appendix for a copy of the claims involved in the appeal.

IX. Evidence Appendix

(none)

X. Related Proceedings Appendix

(none)

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

Date December 8, 2010

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VIII. CLAIMS APPENDIX

The Appealed Claims

1. A test paper comprising a porous membrane having a function of separating an object that should be filtered out from a sample by filtration and carrying thereon a reagent capable of giving a color by reaction with a specified component in the sample,

wherein said porous membrane has a first layer having a surface to which a sample is supplied and a second layer having a surface at which the sample is percolated and measured,

said first layer being made of large-sized pore portions whose section density is 40% or less, with a surface of said first layer being a smooth surface having apertures thereat, said second layer being made of small-sized pore portions whose section density exceeds 40%, with a surface of said second layer having apertures thereat,

wherein said first layer and said second layer together constitute a single membrane portion formed by a single casting operation, and

wherein said porous membrane has a thickness of 50 to 200 μm and a porosity of 60 to 95%, said first layer has an average pore size of 0.5 to 10 μm in the surface thereof, and said first layer is located from the surface of said first layer within a range of 1/5 to 1/2 of a thickness of said porous membrane, and said second layer has an average pore size of 0.1 to 3.0 μm in the surface thereof, and said second layer has a surface glossiness according to JIS Z8741 not higher than 11.

4. The test paper according to Claim 1, wherein a material for said porous membrane is made of polyether sulfone.

5. The test paper according to Claim 1, wherein said sample is a blood and said object that should be filtered out contains blood cells.

6. A porous membrane which comprises a first layer having a surface and a second layer having another surface,

wherein said first layer is made of large-sized pore portions whose section density is 40% or less, with a surface of said first layer being a smooth surface having apertures thereat, said second layer is made of small-sized pore portions whose section density exceeds 40%, with a surface of the second layer having apertures thereat,

wherein said first layer and said second layer together constitute a single membrane portion formed by a single casting operation, and

wherein a membrane thickness ranges from 50 to 200 μm, a porosity ranges from 60 to 95%, said first layer has an average pore size of 0.5 to 10 μm in the surface thereof, and said first layer is located from the surface of said first layer within a range of 1/5 to 1/2 of a thickness of said porous membrane, and said second layer has an average pore size of 0.1 to 3.0 μm in the surface thereof, and said second layer has a surface glossiness according to JIS Z8741 not higher than 11.

7. The porous membrane according to Claim 6, wherein a ratio between the average pore size in the surface of said first layer and the average pore size in the surface of said second layer is in the range of 1 to 6.